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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	0401-UTL-0	7314

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,969	PITTNER ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8 and 33-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8 and 33-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 03/30/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed on 03/30/2005 has been entered. Claims 1, 8, 34-41, 43-44, 46, and 52-53 have been amended. Claims 1, 8, and 33-54 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

The information disclosure statement filed on 03/30/2005 has been considered by the Examiner and a signed copy has been attached to this office action.

Withdrawn Rejections

The rejection of claims 1, 8, 33-37, 42, 47, 51, 52, and 54 under 35 U.S.C. 112, second paragraph, and rejection of claim 42 under 35 U.S.C. 112, second paragraph, as set forth at pages 7-8 of Paper No. 11192004 (mailed on 11/30/2004), have been withdrawn in view of Applicants' arguments.

The rejection of claim 43 under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992), as set forth at pags 8-9 of Paper No.

11192004 (mailed on 11/30/2004), has been withdrawn in view of amended claim that is directed to humans.

The rejection of claims 8, 34-37, 39-41, 43, 44, 46, and 47 under 35 U.S.C. 102(b) as being anticipated by Morley et al (*Life Sci.* 41:2157-2165, 1987), as set forth at page 9 of Paper No. 11192004 (mailed on 11/30/2004), has been withdrawn in view of amended claims that are directed to humans.

The rejection of claims 43, 44, and 46 under 35 U.S.C. 102(b) as being anticipated by Okada et al. (*The Endocrine Society 75th Annual Meeting Programm & Abstract*, page 180, Abstract 520B, 1993), as set forth at pages 9-10 of Paper No. 11192004 (mailed on 11/30/2004), has been withdrawn in view of amended claims that are directed to humans.

The rejection of claim 45 under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (*The Endocrine Society 75th Annual Meeting Programm & Abstract*, page 180, Abstract 520B, 1993), as set forth at pages 12-13 of Paper No. 11192004 (mailed on 11/30/2004), has been withdrawn in view of amended claim.

Claim Rejections under 35 USC § 112, 1st paragraph

(i) The rejection of claims 1, 8, and 33-54 under 35 U.S.C.§112, first paragraph, for scope of enablement, as set forth at pages 3-5 in Paper No. 11192004 (mailed on11/30/2004), is maintained.

At the 3rd paragraph of page 7 of applicants' response filed on 03/30/2005, Applicants argue that Applicants have amended claims 8, 33-36, 43-52, and 54 to recite peripheral administration. The examiner notes that the claims have not been amended so in actuality.

At the bottom of page 7 of applicants' response filed on 03/30/2005, Applicants argue that the specification describes PYY agonists in term of function and structure. Applicants submit that the specification states that PYY agonists may have activity in any of assays described in the specification and describes PYY agonists as having structure similar to PYY.

Applicants' argument has been fully considered, but is not deemed to be persuasive. As noted in the previous office action, claims 1, 8, 33-46, 48-54 are are drawn to methods of administering to a subject PYY or a PYY agonist. The specification defines a PYY agonist as any compound which elicits an effect of PYY to reduce nutrient availability (page 5, lines 24-25). Such agonists can comprise a polypeptide having a functional domain, an active fragment of PYY, a chemical, or a small molecule. PYY agonists may be peptide or non-peptide compounds, and may include PYY agonist analogs, which refer to any compound structurally similar to PYY that have PYY activity (page 6, lines 3-6). Thus, the claims are drawn to a method comprising administration of a genus of structurally undefined PYY agonists.

At the top of page 8 of Applicants' response filed on 03/30/2005, Applicants argue that

U. S. Patent Nos: 5,574,010; 5,604,203, 5,696,093, and 6,046,167 describe PYY agonists. Accordingly, the skilled artisan would read the newly discovered uses of PYY and PYY agonists disclosed in the present application in view of the work in the art about PYY and PYY agonists. Applicants submit that one of skilled in the art would understand that the scope of the claimed invention is directed to the novel uses of PYY and PYY agonists, and not directed to the use of any particular PYY agonist in the methods of the invention. Similarly, one of skilled in the art would understand that the claims are not directed to specific agonists of GLP-1, exendin, or Amylin, but only that these compounds, which are known in the art can be useful in the claimed methods of the invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the cited U. S. Patents do not teach the PYY agonists in the context of reducing nutrient availability, food intake or body weight. The PYY agonists were taught for entirely different purposes, such as inhibiting proliferation of pancreatic tumors in U.S. Patent No. 5,574,010; treating nasal congestion in U.S. patent No. 5,696,093; controlling cell proliferation, nutrient transport, lipolysis, and intestinal water and electrolyte secretion in U. S. Patent No. 5,604,203. Secondly, in order to satisfy the enablement requirement under 35 U.S.C.§112, first paragraph, Applicants are required to teach how to make and use the claimed invention in the disclosure. In the instant case, the specification is required to provide sufficient disclosure for one skilled in the art to make and use the claimed methods. Since agonists are critical for the practice of the methods, the specification is required to provide enablement for the PYY agonists.

Applicants' argument that the scope of the claimed invention is directed to the novel uses of PYY and PYY agonists, and not directed to the use of any particular PYY agonist in the methods of the invention is based upon ill reasoning because the disclosure cannot reasonably provide enablement for the genus of PYY agonists without enabling its species. Likewise, the instant disclosure cannot enable the genus of agonists of GLP-1, exendin, or Amylin without enablement of species.

At the 2nd paragraph of page 8 of Applicants' response filed on 03/30/2005, Applicants argue that while PYY (6-36) and PYY (13-36) may not possess certain functions PYY, they do possess other functions of PYY, such as Y receptor binding, making then PYY agonists. Applicants submit that it is not any one particular function of PYY that makes them useful to the claimed methods.

This has been fully considered, but is not deemed to be persuasive for the following reasons. As noted in the previous office action, it is unpredictable whether a compound that is related to PYY would work in the same manner as that of PYY in view of the complexity of the nature of PYY-related compounds. For example, PYY (6-36) and PYY (13-36), when peripherally administered, do not inhibit gastric acid secretion or pancreatic exocrine secretion (see, e.g., Yoshinaga et al., *Am. J. Physiol.* 263:G695-701, 1992). If, as applicants have argued, a PYY agonist does not necessarily possess a function of inhibiting gastric acid secretion or pancreatic exocrine secretion, how can such a PYY agonist acts to reduce nutrient availability, food intake or body weight? An antagonist may bind Y receptor; but it does not make it a PYY agonist.

At the bottom of page 8 of Applicants' response filed on 03/30/2005, Applicants submit that it is not essential to the methods a PYY agonist has all the same characteristics as PYY. Applicants argue that PYY (3-36), for instance, does not appear to have the hypertensive effect reported for PYY. Applicants argue that it would not have been undue experimentation for one of ordinary skill in the art, based upon the relevant art and the assays described in the instant disclosure, to determine the PYY agonists that may be useful in the invention. Applicants also argue that valid claim may include inoperative embodiments.

This has been fully considered, but is not deemed to be persuasive for the following reasons. While a PYY agonist, such as PYY (3-36), may not have the exactly same properties or activities, it must share the same functional characteristics of PYY. In the instant case, such a functional characteristics appears to be including reducing nutrient availability, food intake or body weight (see bottom of page 5 of the instant specification for definition of a PYY agonist), which are essential for the present invention. It is noted that a method of screening a PYY agonist does not equate a method of making a PYY agonist. While a claim may include certain inoperative embodiments, the specification must reasonably provide enablement for the claimed invention commensurate in scope with the claim. It is not the case here.

(ii) The rejection of claims 1, 8, 33-46, and 48-54 under 35 U.S.C. 112, first paragraph, for written description, as set forth at pages 6-8 in Paper No. 11192004 (mailed on11/30/2004), is maintained.

At the 3rd paragraph of page 9 of Applicants' response filed on 03/30/2005, Applicants submit the specification describes the function and structure of PYY and PYY agonists. Applicants argue that U. S. Patent Nos: 5,574,010; 5,604,203, 5,696,093, and 6,046,167 describe PYY agonists. Citing case law, Applicants submit that what is known in the art need not be disclosed in detail.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. The Examiner does not take issue with the case law and agrees with the Applicants that what is known in the art need not be disclosed in detail. However, claims 1, 8, 33-46, 48-54 are drawn to methods of administering to a subject PYY or a PYY agonist. The specification defines a PYY agonist as any compound which elicits an effect of PYY to reduce nutrient availability (page 5, lines 24-25). Such agonists can comprise a polypeptide having a functional domain, an active fragment of PYY, a chemical, or a small molecule. PYY agonists may be peptide or non-peptide compounds, and may include PYY agonist analogs, which refer to any compound structurally similar to a PYY that has PYY activity (page 6, lines 3-6). Thus, the claims are drawn to a method comprising administration of a genus of structurally undefined PYY agonists. The specification fails to provide any critical structural feature to adequately describe the genus of PYY agonists that may be administered in the claimed method. The cited U. S. Patents do not teach the PYY agonists in the context of reducing nutrient availability, food intake or body weight. The prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed PYY agonists being identical to those instantly claimed.

At the 4th paragraph of page 9 of Applicants' response filed on 03/30/2005, Applicants, citing case law, argue that if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, the adequate description requirement is met. Applicants further submit that the standards may be different if the invention were drawn to composition claims of PYY agonist. The present invention is drawn to a method of using PYY agonists, the description provided in the specification as well as the PYY agonists that were known at the time of filing would have provided the skilled artisan with reasonably clarity as to the scope of the claimed invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the PYY agonist recited in the claims is not a nuance; rather it is critical for the practice of the instantly claimed methods. Secondly, the claims are drawn to a method comprising administration of a genus of structurally undefined PYY agonists. The specification fails to provide any critical structural feature to adequately describe the genus of PYY agonists that may be administered in the claimed method. The specification merely discloses two compounds, PYY and PYY (3-36), which are not sufficiently representative of the claimed genus of PYY agonists. There is no defined relation between function and structure of the PYY agonists. There is even no identification of any particular portion of the structure that must be conserved. The prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed PYY agonists being identical to those instantly claimed. Moreover, regardless whether the claims are drawn to a composition

or a method of using the composition, the standards of written description is the same. Here in the instant case, a sufficient written description is required for the genus of PYY agonists recited in the method.

For the reasons above, the rejection of claims 1, 8, 33-46, and 48-54 under 35 U.S.C. 112, first paragraph, for written description, is maintained.

Claim Rejections under 35 USC § 112, 2nd paragraph

Claims 1, 8, 33-42, and 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claims 1, 8, 34-41, and 52-54 are indefinite because each claim recites a limitation, "desirous of reducing caloric efficiency". It is unclear how such a limitation, which represents a mental process, limits the subject recited in the claims. Claims 33, 42, and 47-51 are rejected as dependent claims.

Claim Rejections Under 35 U. S. C. § 102 (b)

(i) The rejection of claims 1, 8, 33-42, 47-49, and 52-54 under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992), as set forth at pags 8-9 of Paper No. 11192004 (mailed on 11/30/2004), is maintained.

At the middle of page 12 of Applicants' response filed on 03/30/2005, Applicants argue that the claims 1, 8, 33-42, 47-49, and 52-54 are narrowed by the amendment to the subject population. This is not persuasive because the limitation "desirous of reducing caloric efficiency" is considered to be indefinite. It is unclear how such a mental process limits the subject population.

At the bottom of page 12 of Applicants' response filed on 03/30/2005, Applicants argue that Yoshinaga et al do not inherently anticipate the claimed invention. Applicants submit that Yoshinaga et al. teach a method of inhibiting pancreatic exocrine and gastric acid output in dogs, but do not teach or imply that PYY or PYY (3-36) has an effect on caloric efficiency, nutrient availability, appetite, food intake, or weight.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Yoshinaga et al. teach a method of inhibiting pancreatic exocrine and gastric acid output, which are necessarily liked to other properties of PYY or PYY agonists, such as caloric efficiency, nutrient availability, appetite, food intake, or weight (see bottom of the instant specification). Moreover, since Yoshinaga et al. teach a method of administering to a subject the same agent (PYY or PYY agonist) in the same dose as that of the instantly claimed method, the intended uses and properties of the PYY or PYY agonist recited in the claims are inherent to the method taught by Yoshinaga et al. The property or functional activity is inherent to the structure of a molecule because it is well established that a property or function of a molecule depends upon its structure. It is noted that recognition by a person of ordinary skill in the art is not required to show

anticipation by inherency (*Schering Corp. v. Geneva Pharmaceuticals, Inc.,* No. 02-1540 (Fed. Cir. Aug. 1, 2003)).

(ii) The rejection of claims 1, 33, 38, 42, 48-50, and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Morley et al (*Life Sci.* 41:2157-2165, 1987) is maintained.

Beginning at the 2nd paragraph of page 12 of Applicants' response filed on 03/30/2005, Applicants argue that Morley, when viewed as a whole, does not teach a method of reducing body weight by peripheral administering PYY. Applicants submit that one of ordinary skill in the art, reading Morley, would not believe that the described experiment supported its conclusion because the control mice gained weight in all the experiments except that of PYY administration, which invalidate the experimental data.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Morley et al. clearly teach that peripheral administration of PYY caused weight loss (see e.g., Abstract), which is supported by experimental data. For example, Fig. 5 shows that the control mice gained weight, whereas PYY-treated mice lost weight.

At the bottom of page 12 of Applicants' response filed on 03/30/2005, Applicants argue that the magnitude of the weight difference between the control mice and PYY-administered is similar to the magnitude of the weight difference between control mice and mice administered compounds Morley reports as having no effect on weight. Thus,

one of ordinary skill in the art would be further disinclined to give any weight to Morley's conclusion. Applicants' argument has been fully considered, but is not deemed to be persuasive because the weight difference between the control mice and PYY-administered was shown to be statistically significant (see, legend to Fig. 5). It is improper to merely compare the body weight difference in unrelated experiments.

At the 2nd paragraph of page 12 of Applicants' response filed on 03/30/2005, Applicants argue that the skilled artisan would be even more disinclined to believe Morley's unsupported conclusion based upon his/her knowledge of the art because around the time Morley was published, it was generally believed that PYY and NPY were orexigenic agents, citing a number of references, including one Morley's earlier reference. Accordingly, Applicants submit that the instant claims drawn to PYY and PYY agonists are not anticipated by Moreley et al., as Morley does not provide credible evidence for one of ordinary skill in the art to go against prevailing beliefs of the time.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, as noted above, Morley's conclusion that peripheral administration of PYY caused weight loss is supported by experimental data shown in Fig. 5A. Secondly, the teaching that centrally administered PYY stimulated gastric acid secretion, which is opposite to those described for peripherally injected PYY, is not contradictory to the effect of PYY when peripherally administer because the routes of administration are different. Thus, from the recognition of PYY as being a orexigenic agent when centrally administer in the Morley's earlier study to the more recent study

that recognized that peripheral administration of PYY caused weight loss is a logic evolution of the knowledge in the prior art. Moreover, other references cited by Applicants do not provide evidence showing that PYY does not act to reduce body weight loss when administered peripherally.

(iii) The rejection of claims 1, 8, 33-42, 47-50, and 52-54 under 35 U.S.C. 102(b) as being anticipated by Okada et al. (*The Endocrine Society 75th Annual Meeting Prograpm & Abstract*, page 180, Abstract 520B, 1993) is maintained.

At the 3rd paragraph of page 14 of Applicants' response filed on 03/30/2005, Applicants submit that Okada et al. does not teach that PYY had an effect on caloric efficiency, nutrient availability, appetite and food intake of non-high fat foods, or weight. Accordingly; Okada et al cannot inherently anticipate the use of PYY and PYY agonists for affecting caloric efficiency, nutrient availability, appetite and food intake of non-high fat foods, or weight.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Okada et al. teach a method of administering to a subject the same agent (PYY) in the same dose as that of the instantly claimed method, all the intended uses and properties of the PYY or PYY agonist recited in the claims are inherent to the method taught by Okada et al. et al.

Claim Rejections Under 35 U. S. C. §103 (a)

(i) Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al., as applied to claims 1, 8, 33-42, 47-50, and 52-54, in view of Naslund et al. (Int. J. Obes. Relat. Metab. Disord. 23:304-311, 1999), as set forth at pages 11-12 of Paper No. 11192004 (mailed on 11/30/2004), is maintained.

At the bottom of page 15 of Applicants' response filed on 03/30/2005, Applicants submit that Naslund cannot cure the deficiency of Okada and thus cannot render claim 51 unpatentable. This is not found to be persuasive for the reasons set forth in the paragraph immediately above.

(ii) The rejection of claim 51 under 35 U.S.C. 103(a) as being unpatentable over Morley et al (*Life Sci.* 41:2157-2165, 1987), as applied to claims 1, 33, 38, 42, 48-50, and 52-54, and further in view of Naslund et al. (Int. J. Obes. Relat. Metab. Disord. 23:304-311, 1999), as set forth at pages 12-13 of Paper No. 11192004 (mailed on 11/30/2004), is maintained.

At the top of page 16 of Applicants' response filed on 03/30/2005, Applicants submit that Naslund cannot cure the deficiency of Morley and thus cannot to render claim 51 unpatentable. This is not found to be persuasive for the reasons set forth above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Examiner
June 21, 2005